



NEWSLETTER

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Improvements at IRB Company, Inc.

In order to stay in compliance with regulations, IRB Company, Inc. is in the process of improving some of our forms.

One of our new forms will be the Site Information form. This will take the place of the Site Change worksheet and Waiver form.

This new and improved form will have questions regarding site resources and staffing. These questions will help us and our research partners provide the highest ethical standards for human subjects research.

Who are the Investigators and what are their responsibilities?

The HHS regulations at 45 CFR part 46 use the term “investigator” to refer to an individual performing various tasks related to the conduct of human subjects research activities, such as obtaining informed consent from subjects, interacting with subjects, and communicating with the IRB. For the purposes of the HHS regulations, OHRP interprets an “investigator” to be any individual who is involved in conducting human subjects research studies. Such involvement would include: obtaining information about living individuals by intervening or interacting with them for research purposes; obtaining identifiable private information about living individuals for research purposes; obtaining the voluntary informed consent of individuals to be subjects in research; and studying, interpreting, or analyzing identifiable private information or data for research purposes.

Investigators can include physicians, scientists, nurses, administrative staff, teachers, and students, among others. Some research studies are conducted by more than one investigator, and usually one investigator is designated the “principal investigator” with overall responsibilities for the study. In every human subjects research study, investigators have certain responsibilities regarding the ethical treatment of human subjects.

Investigators play a crucial role in protecting the rights and welfare of human subjects and are responsible for carrying out sound ethical research consistent with research plans approved by an IRB.

Along with meeting the specific requirements of a particular research study, investigators are responsible for ongoing requirements in the conduct of approved research that include, in summary: obtaining and documenting informed consent of subjects or subjects’ legally authorized representatives prior to the subjects’ participation in the research, unless these requirements have been waived; obtaining prior approval from the IRB for any modifications of the previously approved research, including modifications to the informed consent process and document, and ensuring that progress reports and requests for continuing review and approval are submitted to the IRB in accordance with the policies, procedures, and actions of the IRB as referenced in the institution’s OHRP-approved Federalwide assurance. In certain circumstances, investigators also would be responsible for meeting the following additional regulatory requirements: providing to the IRB prompt reports of any unanticipated problems involving risks to subjects or others ; reports of serious or continuing noncompliance with regulations or the requirements or determinations of the IRB and keeping certain records as required by the HHS regulations for at least three years after completion of the study.